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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,440	07/01/2003	Neil Berinstein	API-02-11-US	1959

7590 12/03/2008
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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/611,440	Applicant(s) BERINSTEIN ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 9-11, 14-16, 19-21, 24-26, 29, 30, 40-44, 47-49, 52-54, 57-59 and 62-66 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims pending in the application are 1,4-6,9-11,14-16,19-21,24-26,29,30,40-44,47-49,52-54,57-59 and 62-66.

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DETAILED ACTION

Claims 1, 4, 5, 9, 10, 14, 15, 19, 20, 24-26, 29, 30, 44, 47, 48, 52, 53, 57, 58, 62-66 have been amended. Claims 31 and 34-39 have been canceled. Claims 1, 4-6, 9-11, 14-16, 19-21, 24-26, 29, 30, 40-44, 47-49, 52-54, 57-59 and 62-66 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 9-11, 14-16, 19-21, 24-26, 29, 30, 40-44, 47-49, 52-54, 57-59 and 62-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 44 have been amended to limit the administered nucleic acid to the full length SEQ ID NO:1, or the nucleic acid sequence encoding the full length SEQ ID NO:2, with the qualifier that administration of the vector comprising the nucleic acid sequences induces a T-cell response against the BFA4 protein. The specification as filed described a T cell response only in the context of BFA4 peptides. the specification failed to describe a T cell response to the administration of the full length protein encoded by SEQ ID NO:2. One of skill in the art would reasonable conclude that applicant was not in possession of the claimed invention at the time of filing.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 4, 5, 21, 24, 25, 26, 29, 30, 44, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gish et al (U.S. 6,780,586, reference of the IDS filed August 16, 2006) in view of Ghose et al (Human Gene Therapy, 2000, Vol. 11, pp. 1289-1301, cited in a previous Office action).

Gish et al teach a method of eliciting an immune response in an individual comprising the administration of a nucleic acid comprising a sequence encoding BFA4 (column 3, lines 41-48). SEQ ID NO:1 of Gish et al is identical to the instant SEQ ID NO:1. Gish et al do not teach a pox virus expression vector comprising the sequence encoding BFA4.

Ghose et al teach that canary pox vector are attractive platforms for expression of immunotherapeutic genes in various vaccination platforms including. Ghose et al teach that canary pox or ALVAC vectors are able to infect a wide variety of cell types with a high efficiency of infection, the vectors can accommodate large inserts, the vectors are not mutagenic to the cell they infect, and in addition the vectors are replication defective in non-avian cells. (page 290, first column, third full paragraph). Ghose et al teach that use of canary pox virus in cancer immunotherapy is becoming more widespread. Ghose et al teach that recombinant ALVAX vectors encoding tumor antigens are able to effectively infect antigen-presenting cells thereby causing stimulation of T cells, including CTL in humans (page 290, first column to second column, bridging paragraph). Gosh et al teach a greater anti-tumor response in mice vaccinated with an ALVAC vector additionally expressing B-7 and Il-12 respectively (page 1296, second column, top paragraph).

It would have been prima facie obvious at the time that the claimed invention was made to administer a canary pox vector encoding BFA4 to evoke a T cell response. One of skill in the art would have been motivated to do so by the teachings of Ghose et al on the advantages of a canary pox vector for the administration of antigens. One of skill in the art would have been further motivated to provide the vector with a nucleic acid encoding B7 or Il-12 because ALVAC expression of said nucleic acids

All claims are rejected.

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All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants argument. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643